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1st Inventor:	Sharon Mi Lyn Tan	Art Unit:	1615
Serial No.:	10/631,871	Examiner:	Azpuru, Carlos A.
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Title: LATEX MEDICAL ARTICLES FOR RELEASE OF ANTIMICROBIAL AGENTS

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REPLY BRIEF UNDER 37 C.F.R. §41

Sir:

This is a reply pursuant to 37 C.F.R. §41 in response to the Examiner's Answer mailed on June 22, 2010, in the appeal from the final decision of the Examiner mailed June 26, 2009 ("Final Office Action"), in the above-identified application rejecting Claims 1-23.

This Reply Brief is filed within two (2) months of the Examiner's Answer mailed June 22, 2010, and is timely submitted. Attached to this Reply Brief is a copy of all the claims involved in this appeal.

Any fees deemed to be due may be charged to deposit account No. 50-1047.

Appellants respectfully request that the Board of Patent Appeals and Interferences reverse the Examiner's rejection of the claimed subject matter.

I. REAL PARTY IN INTEREST.

The statement contained in the Appeal Brief identifying the real party in interest is incorporated herein by this reference.

II. RELATED APPEALS AND INTERFERENCES.

The statement contained in the Appeal Brief indicating that there are no related appeals or interferences for this application or any related co-pending applications is incorporated herein by this reference.

III. STATUS OF THE CLAIMS.

The statement contained in the Appeal Brief indicating the status of the claims is incorporated herein by this reference.

IV. STATUS OF AMENDMENTS.

The statement contained in the Appeal Brief indicating the status of amendments is incorporated herein by this reference.

V. SUMMARY OF CLAIMED SUBJECT MATTER.

The summary of the invention contained in the Appeal Brief is incorporated herein by this reference.

VI. GROUNDS OF REJECTION TO BE REVIEWED UPON APPEAL

The following grounds of rejection are presented for review:

A. The rejection of Claims 1-23 under 35 U.S.C. §103(a) based on Umemura in view of Trogolo and McGlothlin. Appellant notes an error in the Examiner's Answer Brief, which refers to the rejection of claims 1-22 under 35 U.S.C. §103(a), whereas the correct rejection is of Claims 1-23 under§103(a).

VII. ARGUMENT

Claims 1-23-are rejected under 35 U.S.C. 103(a) based on Umemura et al. (U.S. Patent No. 4,902,503) ("Umemura") in view of Trogolo et al (U.S. Patent Application Publication No. 2003/0118664) ("Trogolo") and McGlothlin et al. (U.S. Patent No 6,329,444) ("McGlothlin"). This rejection is in error and should be withdrawn.

According to the Examiner Answer, the inclusion of antimicrobials such as silver in both natural and synthetic rubbers is disclosed by Umemura, along with heat curing. The Examiner recognizes, however, that Umemura not teach the encapsulation of the incorporated antimicrobials, and turns to Trogolo to make up for this deficiency.

The Examiner states (a) that Trogolo teaches the microencapsulation of antimicrobial agents using hydrophilic polymers, with various polymers used for encapsulation being listed, (b) that antimicrobial and encapsulating polymer are blended together at paragraph [0066] in the preparation of microparticles, that inclusion of zeolite containing silver ions is disclosed at [0040],[1] and (c) that overlapping microcapsule diameter is disclosed at paragraph [0057] and clearly overlaps. The Examiner states that Trogolo lacks a specific teaching of adding the antimicrobial microparticles to a rubber, but has a generic teaching of using them in polymers generically in paragraph [0068].

The Examiner further notes that neither Umemura nor Trogolo discloses that medical devices can be made from natural and synthetic rubbers and that these rubbers can be dip molded, but states that McGlothlin discloses both.[2]

Consequently, the Examiner agues that those of ordinary skill would have found it well within their skill to microencapsulate the antimicrobial found in Umemura in view of the teachings of Trogolo which discloses the use of antimicrobial microparticles in various polymers and further to form the instantly claimed medical devices through dip molding as taught by McGlothlin with a reasonable expectation of similar antimicrobial results.

Appellant respectfully disagrees. In the Appeal Brief, Applicant noted, *inter alia*, that, in contrast to the present invention, the primary reference, Umemura teaches the use and importance of dissolved silver antimicrobials such as silver protein in order to avoid latex

[1] Appellant wishes to note that this paragraph pertains to the inclusion of antimicrobial metal ions in zeolite particles, rather than vice versa.

[2]McGlothlin actually teaches away from natural rubber. See McGlothlin throughout, including Abstract.

instability and teaches away from low solubility antimicrobials such as silver carbonate suspensions. Moreover, although Trogolo teaches antimicrobial microcapsules, there is no teaching or suggestion that the antimicrobial microcapsules are suitable in latex compositions. In fact, does not appear to disclose any type of latex whatsoever. Thus, there is no reason that one skilled in the art would combine the antimicrobial microcapsules of Trogolo with the latex compositions Umemura. Moreover, even if the references were combined, there would not be a reasonable expectation of success. For example, one of ordinary skill would not reasonably expect success in using the antimicrobial microcapsules of Trogolo in the latex-based process of Umemura as proposed by the Examiner, because Umemura teaches the use of a dissolved antimicrobial agent in order to avoid latex instability. McGlothlin, which is cited for its teachings regarding synthetic rubber and dip coating does not make up for the deficiencies in Umemura and Trogolo.

In his Answer, the Examiner reiterates, *inter alia* (a) that Umemura is used to teach the inclusion of antimicrobials such as silver in both natural and synthetic rubbers as well as release modulating polymers which fit the definition of "latex" as set forth by Appellant, (b) that Umemura was not used to teach encapsulation of the incorporated antimicrobials, (c) that Trogolo "includes many of the polymers applicant defines as latex,"[3] (d) that Trogolo includes a teaching of microencapsulation of antimicrobials, and (e) that McGlothlin was used to show that the polymers taught by Umemura and Trogolo are well known for use in dip molding.

However, the fact remains that "[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." MPEP 2141.02 (emphasis added), citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Umemura clearly pertains to dissolved silver compositions. Umemura does not teach or suggest the use of particulate solid silver compositions and, in fact, teaches that particulate silver compounds are observed to break emulsions. Col. 2, lines 28-31 and Comparative Example 3.

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[3] This is not understood. Contrary to the Examiner's position, the polymers of Trogolo do not include the term "latex" as it is used by Applicant. As defined in paragraph [0021] of the current specification, a "latex" is "an aqueous polymer dispersion." By "aqueous polymer dispersion" is meant "a dispersion of polymer particles in a water-containing fluid." The term "latex" as defined by Applicant is thus not restricted to a particular polymer; however, it does require "a dispersion of polymer particles in a water-containing fluid." Nothing of the sort is taught by Trogolo.

Trogolo describes antimicrobial particles, specifically microcapsules comprising an inorganic agent coated with a hydrophilic polymer (see Abstract). However, Trogolo does not teach or suggest the use of latexes. Moreover, Trogolo indicates that water in the delivery environment is the vehicle for antimicrobial release via the hydrophilic polymer coating. See paragraphs [0017], [0027]-[0029] and [0049]. "A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton" and such a person is capable of making inferences. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1397 (2007). Here, one of ordinary skill in the art would clearly understand that the microcapsules described in Trogolo are not suitable for use in water-based latex compositions such as those of Umemura, because such an act would, among other things, lead to unwanted release of the antimicrobial agent prior to reaching the delivery environment via the release mechanism described in Umemura. At the very least, one of ordinary skill in the art would have no reasonable expectation of success in adding the microcapsules to Trogolo to the latexes for Umemura.

Conclusion

For at least these reasons, Appellant respectfully submits that the rejection of Claims 1-23 under 35 U.S.C § 103(a) as discussed above are in error and should be reversed, and that Claims 1-23 are patentable over the cited references.

Thus, in view of the above, it is respectfully submitted that reversal of the rejections of record is in order.

Date: August 23, 2010 Respectfully submitted,

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VIII. Claims Appendix

1. A medical article that comprises an antimicrobial region, said antimicrobial region comprising release-modulating microparticles dispersed within a latex polymer, said release-modulating microparticles comprising an antimicrobial agent and being adapted to release the antimicrobial agent, wherein said microparticles comprise a core and an encapsulating layer surrounding said core or wherein the microparticles comprise a material within which the antimicrobial compound is dispersed.

2. The medical article of claim 1, wherein said medical article is selected from gloves, finger cots, supply and drainage tubes, catheters, condoms and contraceptive diaphragms.

3. The medical article of claim 1, wherein said medical article is a balloon catheter.

4. The medical article of claim 3, wherein said antimicrobial region is a balloon sleeve.

5. The medical article of claim 1, wherein said antimicrobial region is heat cured.

6. A medical article that comprises an antimicrobial region, said antimicrobial region comprising release-modulating microparticles dispersed within a latex polymer, said release-modulating microparticles comprising an antimicrobial agent and being adapted to release the antimicrobial agent, wherein said antimicrobial region is vulcanized and wherein either said microparticles comprise a core and an encapsulating layer surrounding said core or wherein the microparticles comprise a material within which the antimicrobial compound is dispersed.

7. The medical article of claim 1, wherein said microparticles comprise an encapsulating layer that surrounds a core comprising said antimicrobial agent.

8. The medical article of claim 1, wherein said microparticles comprise a core and an encapsulating layer surrounding said core, wherein said core comprises said antimicrobial agent, and wherein said encapsulating layer comprises a polymer.

9. The medical article of claim 1, wherein said microparticles comprise a polymer, and wherein said antimicrobial compound is dispersed within said polymer.

10. The medical article of claim 1, wherein said microparticles comprise an inorganic material, and wherein said antimicrobial compound is dispersed within said inorganic material.

11. The medical article of claim 10, wherein said antimicrobial compound is dispersed within pores of said inorganic material.

12. The medical article of claim 1, wherein said microparticles comprise a silver-containing ion exchange material.

13. The medical article of claim 1, wherein said microparticles are silver-containing zeolite particles.

14. The medical article of claim 1, wherein said antimicrobial agent comprises silver.

15. The medical article of claim 1, wherein said latex polymer is formed from a natural latex.

16. The medical article of claim 1, wherein said latex polymer is formed from a synthetic latex.

17. The medical article of claim 16, wherein said synthetic latex is a pseudolatex.

18. The medical article of claim 1, wherein said release-modulating microparticles have an average largest dimension, on a weight average basis, ranging from 0.1 to 100 microns.

19. A process for providing the antimicrobial region of claim 1, comprising: (a) providing a latex comprising said microparticles, (b) contacting said latex with a substrate, and (c) curing said latex thereby forming said antimicrobial region.

20. The process of claim 19, wherein said substrate is a mold that is dipped into said latex.

21. A medical article that comprises an antimicrobial region, said antimicrobial region comprising release-modulating microparticles dispersed within a latex polymer, said release-modulating microparticles comprising an antimicrobial agent and being adapted to release the antimicrobial agent, and said release-modulating microparticles selected from the group consisting of microparticles that comprise an encapsulating region that surrounds a region comprising an antimicrobial agent and microparticles that comprise a polymer having an antimicrobial agent dispersed within said polymer.

22. A medical article that comprises an antimicrobial region, said antimicrobial region comprising release-modulating microparticles dispersed within a latex polymer, said release-modulating microparticles comprising an antimicrobial agent and being adapted to release the antimicrobial agent, and said release-modulating microparticles selected from the group consisting of microparticles that comprise an encapsulating region that surrounds a region comprising an antimicrobial agent and microparticles that comprise a polymer having an antimicrobial agent dispersed within said polymer, wherein said antimicrobial region is vulcanized.

23. The medical article of claim 1, wherein said latex polymer comprises a styrene-isobutylene copolymer.

IX. Evidence Appendix

None.

X. Related Proceedings Appendix

None.